

### III. REMARKS

Reconsideration of the present application as amended is respectfully requested.

#### A. Status Of The Claims

Claims 1-3, and 5-38 are pending in this application. The Examiner's indication that the previous rejection under 35 U.S.C. § 112, second paragraph, is acknowledged with appreciation.

#### C. Rejections under 35 U.S.C. § 102 and § 103

In the Office Action, the Examiner rejected claims 1-3 and 5-38 under 35 U.S.C. § 102(a,b,e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,639,476 to Oshlack et al. (hereinafter "the Oshlack reference"). In the rejection, the Examiner stated that the Oshlack reference "anticipates or alternatively renders obvious compositions (and methods of making and use) within the scope of the presently claimed invention; in which the resulting compositions MUST *inherently* possess *the various pharmacologic parameters ... as presently claimed.*"

This rejection is respectfully traversed. As stated by the Federal Circuit in *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268-69, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991):

*Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.*

Initially, while the Oshlack reference does disclose that hydrocodone is a suitable active agent to be utilized in the formulations disclosed therein, hydrocodone formulations were not utilized in any of the examples of the reference, nor does the reference provide any indication that such a formulation was ever made. Therefore, it is improper for the Examiner to state that

the Oshlack reference inherently discloses the presently claimed pharmacokinetic parameters as one cannot establish the inherent characteristics of a composition that was never made.

Although a hydrocodone formulation can be made in accordance with the Oshlack reference, the reference does not provide exemplification as to specific ingredients, specific quantities, or specific processing parameters to obtain such a hydrocodone formulation. Accordingly, it is respectfully submitted that it is possible to prepare a hydrocodone formulation in accordance with the Oshlack reference to obtain a formulation which provides a  $C_{12}/C_{\max}$  ratio of greater than 0.85, as well as a formulation which provides a  $C_{12}/C_{\max}$  ratio of less than 0.55. Accordingly, it is incorrect to conclude that a formulation providing a  $C_{12}/C_{\max}$  ratio of 0.55 to 0.85 necessarily flows from the disclosure of the Oshlack reference. This reasoning also pertains to the other pharmacokinetic parameters recited in the claims.

Further, if a hydrocodone formulation providing a  $C_{12}/C_{\max}$  ratio of 0.55 to 0.85 (or another claimed pharmacokinetic parameter) were to be prepared in accordance with the Oshlack reference (utilizing the benefit of hindsight provided by the present invention), such a formulation would be the result of an optimization of conditions, as (i) the Oshlack disclosure does not provide exemplification as to specific ingredients, specific quantities, or specific processing parameters to obtain such a hydrocodone formulation and (ii) a value higher or lower than a  $C_{12}/C_{\max}$  ratio of than 0.55 to 0.85 (or another claimed pharmacokinetic parameter) may also be obtained in accordance with the Oshlack disclosure. See *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art.

Further, it is respectfully submitted that the Oshlack reference does not teach, hint or suggest a hydrocodone formulation providing a  $C_{12}/C_{\max}$  ratio of 0.55 to 0.85 as recited in the present claims.

In view of the aforementioned remarks, withdrawal of the Examiner's 35 U.S.C. § 102 (a, b, e) and 35 U.S.C. § 103(a), rejections of claims 1-3, 5-41 is respectfully requested.

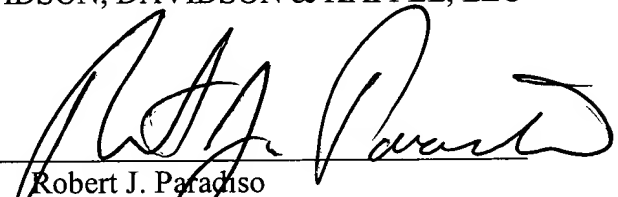
**D. Conclusion**

In view of the arguments presented, it is respectfully submitted that this application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,  
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